

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: G01N 21/27, 21/31	A1	(11) International Publication Number: WO 98/43071 (43) International Publication Date: 1 October 1998 (01.10.98)
(21) International Application Number: PCT/IB97/00292 (22) International Filing Date: 21 March 1997 (21.03.97) (71) Applicant: NELLCOR PURITAN BENNETT INC. (US/US); 4280 Hacienda Drive, Pleasanton, CA 94588 (US). (72) Inventors: BAKER, Clark, R., Jr.; 18493 Magee Way, Castro Valley, CA 94546 (US). YORKEY, Thomas, J.; 3072 Bernard Avenue, San Ramon, CA 94583 (US).	(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.	
(54) Title: METHOD AND APPARATUS FOR ARBITRATING TO OBTAIN BEST ESTIMATES FOR BLOOD CONSTITUENT VALUES AND REJECTING HARMONICS (57) Abstract <p>A method of measuring a blood constituent value using data comprising a single data set comprises: (a) determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and (b) arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.</p>		

 JOINT
 EXHIBIT
 JTX-1546
 CV-00-6506 MRP

JA 22493

 M 1423
 MAS 77823
 CONFIDENTIAL

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SE	Sweden
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TO	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GR	Greece	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GU	Guam	ML	Mali	TR	Turkey
BG	Bulgaria	HN	Honduras	MR	Mauritania	TT	Trinidad and Tobago
BJ	Benin	IL	Israel	MW	Malawi	UA	Ukraine
BR	Brazil	IS	Iceland	MX	Mexico	UG	Uganda
BY	Belarus	IT	Italy	NE	Niger	US	United States of America
CA	Canada	JP	Japan	NL	Netherlands	UZ	Uzbekistan
CF	Central African Republic	KZ	Kazakhstan	NO	Norway	VN	Viet Nam
CG	Congo	KR	Democratic People's Republic of Korea	NZ	New Zealand	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	PL	Poland	ZW	Zimbabwe
CI	Côte d'Ivoire	KN	Republic of Korea	PT	Portugal		
CM	Cameroon	KZ	Kazakhstan	RO	Romania		
CN	China	LC	Saint Lucia	RU	Russian Federation		
CU	Cuba	LI	Liechtenstein	SD	Sudan		
CZ	Czech Republic	LR	Saint Lucia	SE	Sweden		
DE	Germany	LS	Lesotho	SG	Singapore		
DK	Denmark						
EE	Estonia						

MA6 77824
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22494

M 1424

-1-

METHOD AND APPARATUS FOR ARBITRATING TO OBTAIN BEST ESTIMATES
FOR BLOOD CONSTITUENT VALUES & REJECTING HARMONICS

This invention relates to a method and apparatus for measuring physiological parameters, in particular for processing data so that its reliability can be assessed. It relates in particular to a method and apparatus for arbitrating to obtain best estimates for blood constituent values and rejecting harmonics.

Pulse oximeters typically measure and display various blood flow characteristics including the oxygen saturation of haemoglobin in arterial blood and pulse rate. Oximeters pass light through blood perfused tissue such as a finger or an ear, and photoelectrically sense the absorption of light in the tissue. The amount of light absorbed is then used to calculate the amount of the blood constituent (for example oxyhaemoglobin) being measured.

Techniques for calculating blood oxygen saturation levels in haemoglobin are disclosed in International patent application no. IB96/ filed with the present application entitled METHOD AND APPARATUS FOR ADAPTIVELY AVERAGING DATA SIGNALS, which bears the reference P21977A. Information concerning these features of the present invention that is disclosed in those documents is incorporated in the specification of the present application by this reference. The disclosed technique involves assigning varying weights to different measurements, the weighted measurements being averaged to obtain a filtered measurement. It employs Kalman filtering techniques to calculate blood oxygen saturation. Kalman filtering allows one to fit parameters in a least squares sense when the parameters are varying in time.

Other techniques for calculating blood oxygen saturation levels in haemoglobin, in which a harmonic filter is used to reduce noise effects, are disclosed in International patent application no. IB96/ filed with the present application entitled METHOD AND APPARATUS FOR HARMONICALLY FILTERING DATA,

MAS 77825
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22495

M 1425

-2-

entitled METHOD AND APPARATUS FOR HARMONICALLY FILTERING DATA, which bears the reference P21977D. Information concerning these features of the present invention that is disclosed in that document is incorporated in the specification of the present application by this reference.

Techniques for determining pulse rates are disclosed in International patent application no. IB96/ filed with the present application entitled METHOD AND APPARATUS FOR MEASURING PULSE RATE AND SATURATION, which bears the reference P21977B. Information concerning these features of the present invention that is disclosed in this document is incorporated in the specification of the present application by this reference. A technique disclosed in the document involves use of a comb filter to isolate signal energy which corresponds to fundamental and related frequencies.

The present invention provides a technique for assessing signals relating to physiological parameters, in particular blood oxygen saturation and pulse rate, to determine whether and how they are to be displayed. The signals can be derived using techniques of the type that are disclosed in the specifications of the three applications referred to above. The technique of the invention involves arbitrating between possible values of the parameter in question according to a confidence level associated with each value based in a quality metric.

Accordingly, in one aspect, the invention provides a method of measuring a blood constituent value (for example, oxygenated haemoglobin in blood) using data comprising a single data set, which comprises:

- (a) determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the

MAS 77828
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22496

M 1426

-3-

possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

In another aspect, the invention provides apparatus for measuring a blood constituent using a single data set, by applying the method referred to above.

In a further aspect, the invention provides a method of determining a patient's pulse rate using data comprising a single data set corresponding to electromagnetic energy transmitted through the tissue of a patient, the method comprising the steps of:

(a) determining a plurality of possible pulse rates using a plurality of pulse rate estimators, each of the pulse rate estimators using the single data set, each of the possible pulse rates having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible pulse rates with regard to the confidence levels to determine the patient's pulse rate.

In yet another aspect, the invention provides apparatus for determining a patient's pulse rate using a single data set, by applying the method referred to above.

Preferably, the arbitrating step comprises:

(a) comparing the confidence levels for each of the values with the confidence levels for other values; and

MAS 77827
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22497

M 1427

-4-

(b) selecting as the measure of the blood constituent or of the pulse rate (as the case may be) one of the plurality of possible values having a confidence level greater than all other confidence levels by at least a first amount.

Preferably, the arbitrating step comprises linearly interpolating between the plurality of possible values to generate the measure of the blood constituent or the patient's pulse rate (as the case may be) where none of the confidence levels is greater than all other confidence levels by more than a first amount.

When the method is measuring a blood constituent value, it is preferred that the quality metric is selected from the group comprising age of the possible blood constituent value and variance of the possible blood constituent value.

Preferably, in the second method aspect of the invention, the pulse rate estimator determines its corresponding possible pulse rate by:

- (a) defining a comb filter to remove signal energy from the data corresponding to a fundamental frequency and harmonics thereof;
- (b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency; and
- (c) generating the possible pulse rate corresponding to the particular harmonic frequency.

Preferably, the step of determining the harmonic frequency comprises:

- (a) calculating squared noise for the data;

MAS 77828
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22498

M 1428

-5-

- (b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and
- (c) performing a Newton-Raphson search to determine the particular harmonic frequency.

The determination of the pulse rate by the pulse rate estimator can include the steps of:

- (a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and
- (b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

When the method is determining a patient's pulse rate, it is preferred that the quality metric is selected from the group comprising pulse signal shape, signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, arrhythmia probability, and, when there are two wavelengths of electromagnetic energy, a correlation between the data corresponding to the two wavelengths.

The pulse rate estimator in the second method aspect of the invention can determine its corresponding possible pulse rate by:

- (a) comparing the data to a predetermined waveform template;
- (b) identifying a sequence of waveform characteristics indicative of a waveform period;
- (c) averaging a number of successive waveform periods to determine an average waveform period; and
- (d) determining the corresponding possible pulse rate from the average waveform period.

MAS 77829
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22499

M 1429

-6-

The method can include a step of identifying pulse data that is corrupted by motion, and rejecting that data.

The quality metric can then be selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

In a yet further aspect, the invention provides a method of determining a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient, which comprises:

- (a) tracking a fundamental frequency using an adaptive comb filter to filter the data and to thereby generate a first pulse rate, the first pulse rate having a first confidence level associated therewith based on at least one quality metric;
- (b) comparing the data to a predetermined waveform template to generate a second pulse rate, the second pulse rate having a second confidence level associated therewith based on the at least one quality metric; and
- (c) arbitrating between the first and second pulse rates with regard to the first and second confidence levels to determine the patient's pulse rate.

Preferably, the tracking step comprises:

- (a) defining a comb filter to remove signal energy from the data corresponding to the fundamental frequency and harmonics thereof; and
- (b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency.

MAS 77830
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22500

M 1430

-7-

Preferably, the step of determining the harmonic frequency then comprises:

- (a) calculating squared noise for the data;
- (b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and
- (c) performing a Newton-Raphson search to determine the fundamental frequency.

The tracking step can comprise:

- (a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and
- (b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

It might also include a step of filtering the first pulse rate to determine a filtered first pulse rate, for example by a filtering technique such as Kalman filtering.

Preferably, the comparing step of the method comprises:

- (a) identifying a sequence of waveform characteristics indicative of a waveform period;
- (b) averaging a number of successive waveform periods to determine an average waveform period; and
- (c) determining the second pulse rate from the average waveform period.

Preferably, the arbitrating step of the method comprises:

- (a) comparing the first and second confidence levels; and

MA5 77831
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22501

M 1431

-8-

- (b) selecting as the patient's pulse rate one of the first and second confidence levels which is greater than the other of the first and second confidence levels by at least a first amount.

The arbitrating step can comprise linearly interpolating between the first and second pulse rates to generate the patient's pulse rate where neither of the first and second confidence levels is greater than the other of the first and second confidence levels by more than a first amount.

Preferably, the at least one quality metric corresponding to the first confidence level is selected from the group comprising pulse signal shape, signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, and arrhythmia probability.

Preferably, there are two wavelengths of electromagnetic energy, and the at least one quality metric corresponding to the first confidence level comprises a correlation between the data corresponding to the two wavelengths.

Preferably, the at least one quality metric corresponding to the second confidence level is selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

Preferably, prior to the processing step, the method includes the steps of:

- (a) taking the logarithm of a signal representative of the at least one wavelength of electromagnetic energy, thereby generating a first signal;
- (b) band pass filtering the first signal, thereby generating a second signal; and
- (c) normalizing the second signal, thereby generating the data;

MAS 77832
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22502

M 1432

-9-

the tracking step comprising taking the derivative of the data.

The invention can involve reduction of noise effects when measuring a physiological parameter. It can include apparatus for reducing the noise effects which comprises:

means for generating a plurality of measurements derived from at least one wavelength of electromagnetic energy transmitted through living tissue;

means for providing a signal indicative of the at least one wavelength of electromagnetic energy;

means for comparing selected measurements with at least one expected measurement characteristic;

means for assigning one of a plurality of variable weights to each selected measurement based on the comparing step thereby generating a plurality of differently weighted measurements for each wavelength, the variable weights being assigned, in part, in response to a similarity between each selected measurement and a corresponding previous measurement, the variable weights comprising a plurality of different non-zero numbers;

means for averaging a plurality of the differently weighted measurements to obtain a filtered measurement for use in estimating the physiological parameter; and

means for calibrating the system to measure the physiological parameter in response to the signal indicative of the at least one wavelength of electromagnetic energy.

The invention also includes a monitor for measuring a physiological parameter, the monitor being for use with a sensor having emitting means for emitting at least one wavelength of electromagnetic energy, sensing means for sensing the electromagnetic energy and for generating a first signal representative thereof, means for detachably coupling the sensor to the oximeter and for providing communication of signals between the sensor and the oximeter, and means for providing a second signal indicative of the at least one wavelength of electromagnetic energy, the monitor comprising:

HAS 77833
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22503

M 1433

-10-

means for generating a plurality of measurements derived from the first signal;

means for comparing selected measurements with at least one expected measurement characteristic;

means for assigning one of a plurality of variable weights to each selected measurement based on the comparing step thereby generating a plurality of differently weighted measurements, the variable weights being assigned, in part, in response to a similarity between each selected measurement and a corresponding previous measurement, the variable weights comprising a plurality of different non-zero numbers;

means for averaging a plurality of the differently weighted measurements to obtain a filtered measurement for use in estimating the physiological parameter; and

means for calibrating the monitor to measure the physiological parameter in response to the second signal.

There now follows a discussion of preferred methods of processing and displaying the blood oxygen saturation and pulse rate for use on a hospital floor. With metrics that are available from algorithms for measuring oxygen saturation levels and pulse rates, confidence levels for the saturation and the pulse rate values that are calculated can be estimated, thus determining which saturation and which pulse rate of the multiple pulse rates and multiple saturations can be considered reliable, and how long the saturation or pulse rate previously selected should be held when a current estimate is not considered sufficiently reliable.

The present invention can be applied to blood oxygen saturation values calculated using Kalman filtering techniques (with or without cardiac gated averaging) as disclosed in the International patent application no. IB96/ (P21977A) referred to above. Metrics that can be calculated from these algorithms include:

Age: effective averaging period is double this; and

MAS 77834
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22504

M 1434

-11-

Deviation: standard deviation of saturation estimate in saturation points.

The present invention can be applied to pulse rate values calculated using a comb filter as disclosed in the International patent application no. [] referred to above. Metrics that can be calculated from these algorithms include:

Validity: a heuristic metric based on the strength of harmonics in the pulse, i.e., the shape of the pulse;

S/N: signal-to-noise ratio;

Arrhythmia probability: a function of S/N vs. Uncorrelation averaged over time; and

Uncorrelation (IR & red) $\sqrt{1 - \text{crosscorrelation}(\text{IR}, \text{red})^2}$ where crosscorrelation is over an appropriate number of sample points.

Motion flag: set when motion is detected; and

Motion Percent: percentage of motion corrupted patterns detected in the last ten seconds.

The confidence interval for a pulse rate measured using an adaptive comb filter is a function of the validity metric and the arrhythmia probability metric. This space divides into several regions in which one or both metrics are the determining factor in how likely the adaptive comb filter is to be tracking the correct rate.

The Age and Deviation metrics can be used to determine saturation. A general algorithm for calculating the age of the output of an IIR filter having the form

$$\text{Filtered}(n+1) = (1 + W) * \text{Filtered}(n) - W * \text{Raw},$$

MAS 77835
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22505

M 1435

-12-

where the age of Filtered and Raw are known, and Filtered(n) is the value at sample number n, is described by the following steps:

- 1) Increment the age of Filtered by the amount of time elapsed since it was last calculated; and
- 2) $\text{Age of Filtered}(n + 1) = (1 + W) * \text{Age of Filtered}(n) + W * \text{Age of Raw}$

Preferably, the technique of the invention involves evaluation of several properties of the incoming oximetry signal, independent of the confidence metrics for the parameter in question (for example oxygen saturation and pulse rate) to determine whether the signal is actually due to a human pulse and what should appear on the display that is provided. Possible states include:

Disconnect:	when the sensor is unplugged;
No Contact:	when the sensor does not make sufficient contact with the patient;
Pulse lost:	when the pulse disappears and the sensor is still on the patient;
Non-pulse:	when the oximetry signal comes from a signal other than a human pulse because the sensor has fallen off or is seeing an enormous amount of interference;
Pulse Present:	when the oximetry signal comes from a human pulse; and
Not Sure:	a waiting period before declaring a Disconnect or Non-pulse state.

The possible actions in response to the occurrence of these various states are to update the display, hold the current values, or clear the display, for example blanks, dashes, zeroes, etc.

The criteria for the various states are evaluated in the following order:

MAS 77836
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22506

M 1436

-13-

Pulse lost: The % IR modulation is below a threshold for period of seconds, or the criteria for Non-pulse are met and the previous state had been Pulse lost.

Non-pulse: The uncorrelation is high and the percentage of energy above 5 Hz is high, OR the percent IR modulation is low. This criterion has been true for ten seconds continuously. If this criterion has been true for less than ten seconds, the Not Sure state is declared.

Pulse present: The state is not one of the above states.

The criteria for the various display actions are UPDATE when the state is Pulse present, HOLD when the state is Not Sure or No contact, and CLEAR when the state is Disconnect, Pulse lost, or Non-pulse.

The best saturation is displayed when 1) the signal state action is UPDATE, and 2) the best saturation is sufficiently recent. Saturation is held when 1) the conditions for displaying the best saturation are not met, 2) the displayed saturation is less than sufficiently recent, and 3) the signal state action is not CLEAR. Saturation is blanked when 1) the conditions for displaying the best saturation are not met, and 2) the conditions for holding the saturation are not met.

The best heart rate is displayed when 1) the best calculated heart rate has a high confidence, and 2) the signal state action is UPDATE. The heart rate is held when 1) the conditions for displaying the current heart rate are not met, 2) the displayed heart rate is sufficiently recent, and 3) the signal state action is not CLEAR. The heart rate is blanked when 1) the conditions for displaying the current heart rate are not met, and 2) the conditions for holding the heart rate are not met.

MA8 77837
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22507

- M 1437

-14-

CLAIMS:

1. A method of measuring a blood constituent value using data comprising a single data set, which comprises:

(a) determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

2. A method as claimed in claim 1, in which the arbitrating step comprises:

(a) comparing the confidence levels for each of the possible blood constituent values with the confidence levels for other blood constituent values; and

(b) selecting as the measure of the blood constituent one of the plurality of possible blood constituent values having a confidence level greater than all other confidence levels by at least a first amount.

3. A method as claimed in claim 1, in which the arbitrating step comprises linearly interpolating between the plurality of possible blood constituent values to generate the measure of the blood constituent where none of the confidence levels is greater than all other confidence levels by more than a first amount.

MAS 77838
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22508

M 1438

-15-

4. A method as claimed in claim 1, in which the at least one quality metric is selected from the group comprising age of the possible blood constituent value and variance of the possible blood constituent value.

5. A method as claimed in claim 1, in which the blood constituent comprises oxygenated haemoglobin in arterial blood.

6. Apparatus for measuring a blood constituent using a single data set, comprising:

(a) means for determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and

(b) means for arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

7. A method of determining a patient's pulse rate using data comprising a single data set corresponding to energy transmitted through the tissue of a patient, the method comprising the steps of:

(a) determining a plurality of possible pulse rates using a plurality of pulse rate estimators, each of the pulse rate estimators using the single data set, each of the possible pulse rates having a confidence level associated therewith based on at least one quality metric; and

MAS 77839
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22509

M 1439

-16-

(b) arbitrating between the plurality of possible pulse rates with regard to the confidence levels to determine the patient's pulse rate.

8. A method as claimed in claim 7, in which the arbitrating step comprises:

(a) comparing the confidence levels for each of the possible pulse rates with the confidence levels for other possible pulse rates; and

(b) selecting as the patient's pulse rate one of the plurality of possible pulse rates having a confidence level greater than all other confidence levels by at least a first amount.

9. A method as claimed in claim 7, in which the arbitrating step comprises linearly interpolating between the plurality of possible pulse rates to generate the patient's pulse rate where none of the confidence levels is greater than all other confidence levels by more than a first amount.

10. A method as claimed in claim 7, in which one pulse rate estimator determines its corresponding possible pulse rate by:

(a) defining a comb filter to remove signal energy from the data corresponding to a fundamental frequency and harmonics thereof;

(b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency; and

(c) generating the possible pulse rate corresponding to the particular harmonic frequency.

MAS 77840
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22510

M 1440

-17-

11. A method as claimed in claim 10, in which the determining step comprises:

- (a) calculating squared noise for the data;
- (b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and
- (c) performing a Newton-Raphson search to determine the particular harmonic frequency.

12. A method as claimed in claim 10 further comprising the steps of:

- (a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and
- (b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

13. A method as claimed in claim 10, in which the at least one quality metric is selected from the group comprising pulse signal shape, signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, and arrhythmia probability.

14. A method as claimed in claim 10, in which there are two wavelengths of electromagnetic energy, and the at least one quality metric comprises a correlation between the data corresponding to the two wavelengths.

15. A method as claimed in claim 7, in which one pulse rate estimator determines its corresponding possible pulse rate by:

MAS 77841
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22511

M 1441

-18-

- (a) comparing the data to a predetermined waveform template;
 - (b) identifying a sequence of waveform characteristics indicative of a waveform period;
 - (c) averaging a number of successive waveform periods to determine an average waveform period; and
 - (d) determining the corresponding possible pulse rate from the average waveform period.
16. A method as claimed in claim 15, in which the at least one quality metric is selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.
17. A method of determining a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient, which comprises:
- (a) tracking a fundamental frequency using an adaptive comb filter to filter the data and to thereby generate a first pulse rate, the first pulse rate having a first confidence level associated therewith based on at least one quality metric;
 - (b) comparing the data to a predetermined waveform template to generate a second pulse rate, the second pulse rate having a second confidence level associated therewith based on the at least one quality metric; and
 - (c) arbitrating between the first and second pulse rates with regard to the first and second confidence levels to determine the patient's pulse rate.

MA8 77842
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22512

M 1442

-19-

18. A method as claimed in claim 17, in which the tracking step comprises:

(a) defining a comb filter to remove signal energy from the data corresponding to the fundamental frequency and harmonics thereof; and

(b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency.

19. A method as claimed in claim 18, in which the determining step comprises:

(a) calculating squared noise for the data;

(b) calculating a second-derivative of the squared noise with respect to the fundamental frequency; and

(c) performing a Newton-Raphson search to determine the fundamental frequency.

20. A method as claimed in claim 18, in which the tracking step comprises:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and

(b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

MAS 77843
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22513

M 1443

-20-

21. A method as claimed in claim 17, in which the tracking step comprises Kalman filtering the first pulse rate to determine a filtered first pulse rate.

22. A method as claimed in claim 17, in which the comparing step comprises:

- (a) identifying a sequence of waveform characteristics indicative of a waveform period;
- (b) averaging a number of successive waveform periods to determine an average waveform period; and
- (c) determining the second pulse rate from the average waveform period.

23. A method as claimed in claim 17, in which the arbitrating step comprises:

- (a) comparing the first and second confidence levels; and
- (b) selecting as the patient's pulse rate one of the first and second confidence levels which is greater than the other of the first and second confidence levels by at least a first amount.

24. A method as claimed in claim 17, in which the arbitrating step comprises linearly interpolating between the first and second pulse rates to generate the patient's pulse rate where neither of the first and second confidence levels is greater than the other of the first and second confidence levels by more than a first amount.

25. A method as claimed in claim 17, in which the at least one quality metric corresponding to the first confidence level is selected from the group comprising pulse signal shape,

9
HAS 77844
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22514

M 1444

-21-

signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, and arrhythmia probability.

26. A method as claimed in claim 17, in which there are two wavelengths of electromagnetic energy, and the at least one quality metric corresponding to the first confidence level comprises a correlation between the data corresponding to the two wavelengths.

27. A method as claimed in claim 17, in which the at least one quality metric corresponding to the second confidence level is selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

28. A method as claimed in claim 17, which includes, before the processing step, the steps of:

(a) taking the logarithm of a signal representative of the at least one wavelength of electromagnetic energy, thereby generating a first signal;

(b) band pass filtering the first signal, thereby generating a second signal; and

(c) normalizing the second signal, thereby generating the data;

and in which the tracking step comprises taking the derivative of the data.

MA9 77845
CONFIDENTIAL
ATTORNEYS EYES ONLY

JA 22515

M 1445

INTERNATIONAL SEARCH REPORT

 International Application No.
 PCT/IB 97/00292

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 G01N21/27 G01N21/31		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 6 G01N A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 355 880 A (THOMAS ET AL.) 18 October 1994	1,7
A	see the whole document	17
A	EP 0 522 674 A (UNIVERSITY OF NEW MEXICO & SANDIA NATIONAL LABORATORIES) 13 January 1993 see the whole document	1-28
A	WO 96 30742 A (CIBA CORNING DIAGNOSTICS CORP.) 3 October 1996 see the whole document	1-28
A	US 5 435 309 A (THOMAS ET AL.) 25 July 1995 see the whole document	1-28
-/-		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.		<input checked="" type="checkbox"/> Patent family members are listed in annex.
Special categories of cited documents: *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another claim or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search: 25 November 1997		
Date of mailing of the international search report: 08/12/1997		
Name and mailing address of the ISA European Patent Office, P.O. 5818 Paternoster 2 NL - 2200 PH Rijswijk Tel. (+31-70) 340-2040. Tx. 31 651 800 nl, Fax: (+31-70) 340-2016		Authorized officer Bosma, R

Form PCT/ISA210 (secret sheet) (July 1992)

 MAS 77846
 CONFIDENTIAL
 ATTORNEYS EYES ONLY

page 1 of 2

JA 22516

M 1446

Copied from 10779033 on 07/15/2005

INTERNATIONAL SEARCH REPORT

Int. Patent Application No
PCT/IB 97/00292

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 34806 A (LIESENHOFF, TIM ET AL.) 21 December 1995 see the whole document	1-6
A	DE 43 39 067 A (JENOPTIK GMBH) 18 May 1995 see the whole document	1-6

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

MAS 77847
CONFIDENTIAL
ATTORNEYS EYES ONLY

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINE(S) OR MARK(S) ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.